No. 77-956

IN THE

Supreme Court of the United States

October Term, 1977

PARKE, DAVIS & COMPANY,
Petitioner,

v.

JOSEPH A. CALIFANO, Secretary of Health, Education, and Welfare, *et al.*,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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Parke, Davis & Company ("Parke-Davis") petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. A),[1] reversing a preliminary injunction against enforcement actions by the Food and Drug Administration pending an administrative hearing, has not yet been reported. The opinion of the district court granting the injunction (App. B) has not yet been reported.

[1]Because of length, the Appendices are printed in a separate volume.

JURISDICTION

The judgment of the court of appeals (App. C) was entered on October 26, 1977. A timely petition for rehearing was denied on November 23, 1977 (App. D). A stay of mandate under Federal Rule of Appellate Procedure 41(b) was granted on December 5, 1977 (App. E). A motion to vacate that stay was denied on December 14, 1977. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) (1970).

QUESTIONS PRESENTED

1. Whether *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), or *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), controls in a suit for pre-enforcement review of action by the Food and Drug Administration, taken without waiting for a hearing to which petitioner was admittedly entitled, to change the marketing status of a drug back to a prescription basis and to subject petitioner to immediate enforcement action if non-prescription sales were continued.

2. Whether the authority of a federal district court to issue preliminary injunctive relief designed to maintain the *status quo* pending an administrative hearing is defeated by the Government's institution of seizure actions in other courts after the pre-enforcement review proceeding is filed, particularly where consideration of an application for a temporary restraining order had been deferred upon the understanding that no such seizure actions would be filed.

STATUTES AND REGULATIONS INVOLVED

The statutory provisions involved are Sections 201(p), 503(b) and 505 of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. §§ 321(p), 353(b), and 355 (1970 & Supp. V 1975)) and portions of Section 10 of the Administrative Procedure Act (5 U.S.C. §§ 702, 704, 705 and 706 (1970)). The regulatory provisions involved were published in 37 Fed. Reg. 9464 (May 11, 1972); 41 Fed. Reg. 32580 (August 4, 1976); and 41 Fed. Reg. 38312 (September 9, 1976). Pertinent excerpts from these statutory and regulatory provisions are printed in Appendix F.

STATEMENT

The Course of Conduct of FDA

Benylin is a cough syrup made by Parke-Davis containing diphenydramine hydrochloride ("DPH") as the active ingredient. In 1948 the respondent Food and Drug Administration ("FDA") approved Benylin for sale as a "new drug" on a prescription basis.[2] (App. A at 2a.)

On May 11, 1972—in an effort to resolve problems encountered in administering the 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act—the FDA established a procedure for determining administratively both the conditions under which over-the-counter ("OTC") drugs would be generally recognized as safe and effective and thus would not be regarded as "new drugs," and the conditions under which drugs formerly limited to prescription distribution could be approved for OTC sale.[3] In brief, that procedure involved the establishment of independent expert panels appointed by FDA to consider different cate-

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[2]The term "new drug" is defined in § 201(p) of the Federal Food, Drug and Cosmetic ("FDC") Act (21 U.S.C. § 321(p) (1970)). The approval was given pursuant to § 505 (21 U.S.C. § 355 (1970 & Supp. V 1975)). Additional provisions relating to prescription drugs are contained in § 503(b) (21 U.S.C. § 353(b) (1970)).

[3]"Procedures for Classification of Over-the-Counter Drugs," 37 Fed. Reg. 9464 (App. F at 41a-49a). This OTC review procedure is generally described in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 650-53 (1973).

gories of drugs, and to prepare "monographs" describing the purposes for which certain active ingredients would be considered safe and effective. (App. F at 43a-45a.) Insofar as drugs like Benylin were concerned, the expert panel procedure established a second way to secure FDA approval for OTC sales, the first being an amendment to the new drug application ("NDA") that had been approved in 1948.

Thereafter, Parke-Davis sought permission for OTC distribution of Benylin using both available avenues. In response to a notice published by FDA on August 9, 1972, 37 Fed. Reg. 16029, Parke-Davis submitted extensive data on the safety and effectiveness of Benylin to the "cough-cold" expert panel and appeared before it on two occasions. On September 11, 1974, the panel concluded that cough remedies containing DPH, such as Benylin, were safe and effective and suitable for sale OTC. (App. A at 3a.) Shortly thereafter, Parke-Davis filed a supplemental NDA seeking formal approval of OTC sale of Benylin in accordance with the expert panel's conclusion.

Three months later, on February 28, 1975, Parke-Davis requested FDA either to approve its supplemental NDA for OTC sale of Benylin or else to advise that OTC sale would not result in regulatory action (JA 20a-21a).[4] FDA gave two responses. The first closed off the supplemental NDA route by stating that no action on the NDA would be taken until completion of review by the "OTC Cough and Cold Panel" (JA 18a). A week later, on March 16, 1975, however, FDA's second response opened the way for OTC sales of Benylin under the OTC review process. FDA advised Parke-Davis that in view of the conclusion of the expert panel "there would be almost no possibility that we would institute legal action at this time" (JA 23a). This advice was one of the informal exemptions which

[4]This and similar references are to the Joint Appendix below, a copy of which has been lodged with the Clerk of this Court.

FDA was giving at the time pending completion of the OTC review.[5] Pursuant to this "*de facto* approval" (App. B at 17a), Parke-Davis changed its labeling and distribution procedures and began OTC marketing of Benylin in September 1975. (App. B at 22a.)

On September 9, 1976, FDA published in the Federal Register the cough-cold expert panel's proposed monograph, which reaffirmed the panel's earlier conclusion that DPH was safe and effective and suitable for OTC sale. 41 Fed. Reg. 38312 (App. F at 57a-90a). The FDA Commissioner did not dissent from the panel's careful and extensively documented recommendation.[6] Under the regulations then, and now, in effect, publication of the monograph without dissent constituted formal approval of the OTC

[5]The practice of granting informal exceptions after favorable panel conclusions was noted in proposed rules published on December 4, 1975, regarding OTC marketing (40 Fed. Reg. 56675). FDA there explained that, in the light of the expert panel recommendations, some manufacturers had initiated OTC marketing of prescription drugs "pending completion of the OTC drug review, relying on previous informal expressions of general Food and Drug Administration policy." DPH was noted as one of the prescription products which were being so marketed OTC and the proposal stated that such products "are under review to determine their regulatory status." *Id.* at 56676. Final regulations resulting from that proposal were published on August 4, 1976 (Marketing Status of Ingredients Recommended for Over-the-Counter Use, 41 Fed. Reg. 32580; App. F at 50a-56a). They provided that a prescription drug classified by an OTC review panel as safe and effective could be marketed OTC after publication of the panel's proposed monograph in the Federal Register (unless the FDA Commissioner dissented from the monograph), subject to the risk of action by FDA to change the drug's status. These final regulations again recognized that products containing DPH were being marketed OTC. (App. F at 51a-53a.)

[6]In the preamble FDA did state that it was deferring "decision on the Panel's recommendation that diphenhydramine be considered generally recognized as safe and effective for OTC use as an antitussive until the agency has had an opportunity to rule on a supplemental NDA now pending for OTC use . . . ." (App. F at 61a.) That was a reversal of the position previously taken by FDA in March 1975 when it advised Parke-Davis that consideration of the supplemental NDA would be deferred pending outcome of the OTC review process.

marketing of Benylin (as always, subject to further action by FDA)—the same marketing status FDA had informally approved in March 1975.[7]

On November 22, 1976, FDA issued two notices that threatened to change the marketing status of Benylin back to a prescription basis. One notice announced that FDA now disagreed with the expert panel's conclusion and asserted that products containing DPH (such as Benylin) would be subject to regulatory action if marketed OTC. The other notice stated that FDA proposed to deny Parke-Davis' supplemental NDA for OTC sale and that Parke-Davis was entitled to a hearing thereon.[8] Two days later, on November 24, in a telegram to Parke-Davis requesting the company to stop OTC distribution and to recall existing stocks, FDA reiterated its view that as a result of the November 22 notices "the marketing status of the product *reverts* . . . to prescription sale." (App. H at 102a, emphasis added.)

The Proceedings Below

Faced with these enforcement threats, Parke-Davis began this action in the Eastern District of Michigan on November 29, 1976, filing a complaint for declaratory and injunctive relief and applying for a temporary restraining order.[9] In a brief chambers conference on that day, government counsel, who had contacted the FDA Office of General Counsel, gave no indication that any enforcement actions were imminent. The district court fixed December 3 for hearing on injunctive relief, with the understanding that the status quo would be maintained in the meantime.[10]

[7]See footnote 5, *supra*, and the regulations published on August 4, 1976 (App. F at 50a-56a), described therein.

[8]JA 50a-53a, 36a-48a. These notices were subsequently published on November 30, 1976, 41 Fed. Reg. at 52536 and 52537.

[9]The jurisdiction of the District Court was based on 28 U.S.C. § 1331(a) (1970). (App. B at 18a.)

[10]Tr. of Dec. 1, 1976 Hearing at 17-23.

However, at that time, unknown to the district court and Parke-Davis, FDA was preparing seizure actions and on the next two days—November 30 and December 1, 1976—seizures were effected in district courts in Texas, Illinois, and Minnesota. Understandably irked by these seizure actions, which looked to it "like dirty pool,"[11] the district court in Michigan granted Parke-Davis' application for a temporary restraining order on December 1, 1976. (App. B at 14a-15a.) After further hearings on December 3 and 8, the district court issued a preliminary injunction restraining FDA from instituting enforcement proceedings against Benylin until 30 days after FDA took final action in the administrative hearing to determine the status of Benylin.[12] (App. A at 7a.)

In its memorandum opinion the district court concluded that Parke-Davis was not entitled to a declaratory judgment that Benylin was not a "new drug", or to a determination that the drug was not limited to prescription sale, ruling that those "issues are currently under consideration by the FDA which has primary jurisdiction over such matters" (App. B at 20a). However, the court concluded that preliminary injunctive relief to preserve the status quo was proper under the Administrative Procedure Act and this Court's decision in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967). It held that FDA had acted arbitrarily and capriciously in purporting to change the marketing status of Benylin in the absence of a final agency decision after a hearing on the supplemental NDA. "This is particu-

[11]*Id.* at 22.

[12]In response to the November 22, 1976 notice that FDA proposed to deny the supplemental NDA for OTC sales of Benylin, Parke-Davis had requested a hearing on December 7, 1976. The oral phase of that administrative hearing has been completed and briefs to the administrative law judge were simultaneously filed on December 15, 1977. Exceptions from his initial decision can be taken to the Commissioner of Food and Drugs whose decision can be reviewed by a court of appeals pursuant to § 505(h) of the FDC Act.

larly true," said the court, "where, as here, the advisory panel made a thorough study of the drug, its recommendation is supported by the affidavits of several other eminent experts in the field, and, in contrast, the Commissioner's tentative decision not to permit OTC sale is rather incompletely supported" (App. B at 22a).[13] The district court found that Parke-Davis would be irreparably injured by financial losses to be incurred in recalling and relabeling its supplies of Benylin, and by the adverse publicity that would accompany either voluntary recall or seizure. Finally, the court found that there was no countervailing public interest "since it is acknowledged by defendants that OTC sale of Benylin presents no imminent hazard to the public health" and since "Benylin has been sold OTC in Canada for twenty-seven years and in the United States for over a year apparently without creating any hazard" (App. B at 23a).[14]

FDA and the other respondents appealed from the preliminary injunction and sought to stay it pending appeal. The court of appeals denied the stay application on April

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[13]FDA admitted in the November 22, 1976 notice of its proposal to deny Parke-Davis' supplemental NDA that the information on which its disagreement with the expert panel rested "is inconclusive and should be developed in a hearing." JA 45a; 41 Fed. Reg. at 52538.

[14]From the bench the district court gave this further explanation for its injunction (JA 138a-139a):

> "I find that under the circumstances that have been developed here and which are not in conflict, that the course of conduct of the Commissioner in permitting Parke-Davis to market this drug over the counter, and having allowed it to do so for many months and now suddenly reversing that without an administrative hearing is arbitrary action and ought to be enjoined.
>
> "It is my position that the Commissioner should make this decision and that it ought to be done as expeditiously as possible. I do not believe that the public interest is in any way harmed by having the status quo preserved while that administrative hearing proceeds."

15, 1977. After argument in June, it reversed the district court. In its opinion (App. A), the court of appeals held: (1) that the case was controlled by this Court's decision in *Ewing* v. *Mytinger & Casselberry*, 339 U.S. 594 (1950), rather than *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967); (2) that under *Ewing* the district court had no jurisdiction to review FDA's decision to initiate enforcement; and (3) that the subsequent seizure actions provided an adequate remedy for Parke-Davis to review the actions of FDA.

REASONS FOR GRANTING THE WRIT

This case presents an important question, which was wrongly decided below, concerning the right to pre-enforcement review and injunctive relief in the context of a major regulatory program, the OTC drug review being conducted by FDA. In denying pre-enforcement review, the court of appeals erroneously held that the case was governed by this Court's decision in *Ewing* v. *Mytinger & Casselberry*, 339 U.S. 594 (1950), instead of this Court's decision in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967). And in holding that enforcement actions should not have been enjoined pending completion of the administrative hearing on the status of Benylin, the decision below conflicts with action taken by the lower courts, not objected to by the government, and upheld by this Court, in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973). On this point the decision below also conflicts with the Tenth Circuit's decision in *Rutherford* v. *United States*, 542 F.2d 1137 (1976).

1. The Court Of Appeals Wrongly Held That This Case Is Governed By This Court's Decision In *Ewing* Instead Of This Court's Decision in *Abbott Laboratories*. This case is governed by *Abbott Laboratories*, not *Ewing*.

Plaintiff in the *Ewing* case was seeking an "unheard-of form of relief" (*Abbott Laboratories*, 387 U.S. at 148)—review of the facts underlying, and an injunction against, a finding of probable cause to seize misbranded goods. The determination of probable cause had no effect in and of itself, as this Court carefully pointed out both in *Ewing* (339 U.S. at 598-99) and in *Abbott Laboratories* (387 U.S. at 146-48); it served only to permit FDA to recommend enforcement action to the Justice Department. Here, in contrast, pre-enforcement review is sought of a course of conduct by FDA which, even if enforcement actions had not been initiated, adversely affected the status of Parke-Davis' product, Benylin. The administrative conduct Parke-Davis challenged was the purported change in "the marketing status" of Benylin back "to prescription sale" (App. H at 102a), contrary to the recommendation of the expert panel and without waiting for the conclusion of the administrative hearing, to which Parke-Davis was entitled and which it requested, on whether Benylin should be sold only on a prescription basis. It was this course of conduct—not merely, as the court of appeals said, "the decision of the FDA to initiate enforcement actions" (App. A at 11a)—that the district court found to be arbitrary and capricious. (App. B at 22a-23a; *see also* pp. 7-8 & n.14, *supra*.)

Judicial review of the FDA actions challenged by Parke-Davis is well within the scope of the pre-enforcement review this Court approved in *Abbott Laboratories*. First, review was sought, not of the facts underlying the exercise of prosecutorial discretion, but of a "purely legal" question (387 U.S. at 149): whether FDA's admitted course of conduct was arbitrary and capricious. Second, the agency action sought to be reviewed was final within the pragmatic test of *Abbott Laboratories* (*id.* at 149-52):

FDA itself asserted that its action made the "marketing status" of Benylin "revert" from OTC to prescription sale, and FDA stated that it intended to take enforcement action based on its new view that OTC sales were not permitted. Third, the action sought to be reviewed had a direct and immediate impact on Parke-Davis (*id.* at 152-53) because, absent judicial relief, the company faced the dilemma of changing over to prescription sale with attendant expense and other irreparable injury or else risking prosecution if it continued OTC sale. Finally, pre-enforcement review would not delay or impede effective enforcement of the FDC Act (*id.* at 154-56) because FDA had an opportunity to oppose injunctive relief to Parke-Davis and to seek an injunction itself, and, as noted at pages 7-8, *supra*, there was no showing or claim that delay would be detrimental to the public health or safety.

The court of appeals attempted to distinguish *Abbott Laboratories* and FDA cases following it[15] on two grounds, neither of which is satisfactory. The first ground was that "Benylin has never received final approval as an over-the-counter drug" (App. A at 12a). That purported distinction overlooks the fact that OTC sales of Benylin had received both *de facto* and formal approval prior to November 22, 1976. Any drug product, whether it has received final or interim approval, always faces the prospect that FDA may seek to change its status. In any event, this Court held in *Abbott Laboratories* that finality for purposes of pre-enforcement review is a pragmatic and flexible concept, and a statement of agency intentions with which "compliance" is "expected"—like the November 22 notices and the November 24 telegram—can constitute final agency action (387 U.S. at 152).

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[15] *E.g.*, *Upjohn Co.* v. *Finch*, 303 F. Supp. 241 (W.D. Mich. 1969); *American Home Products Corporation* v. *Finch*, 303 F. Supp. 448 (D. Del. 1969).

The second asserted ground for distinction—that "in this case enforcement proceedings were pending in other jurisdictions when the district court issued its injunctive orders" (App. A at 12a)—is also unsound. It rests upon an erroneous premise. The enforcement actions began after Parke-Davis filed its lawsuit, and were pending when the preliminary injunction issued only because the district court and Parke-Davis had been led to defer consideration of the application for a temporary restraining order because of an understanding that no enforcement action would be taken prior to the hearing fixed for December 3, 1976. When that understanding was breached, the district court acted promptly to enjoin FDA and to direct it to take steps to cause the release of the seized Benylin.[16] In any event, the filing of seizure actions cannot be regarded as ousting the pre-enforcement review court of its authority. Were that the rule, all the government would have to do to prevent the kind of pre-enforcement review this Court approved in *Abbott Laboratories* would be to file enforcement actions against any person with the temerity to sue it.[17] And, as this Court held in *Abbott Laboratories*, requiring a drug company to forgo pre-enforcement review in favor of defense of a seizure action can produce severe and needless harm to the company (387 U.S. at 153).

In short, the court of appeals followed the wrong precedent, and its decision, if it stands, will encourage further and multiple litigation whenever pre-enforcement review of a major federal regulatory program is sought. Review by this Court is appropriate for these reasons, and because confusion over the relationship between *Ewing* and

[16]Despite the order to do so, the government has never released the Benylin it seized before the restraining order was issued.

[17]*Compare, e.g., In re Corporate Patterns Report Litigation*, 432 F. Supp. 274, 287-89 (D.D.C. 1977), where pre-enforcement review and an enforcement action were heard together, and a government motion to dismiss the pre-enforcement action on jurisdictional grounds was denied.

Abbott Laboratories is evident in cases decided by other lower federal courts as well.[18]

2. The Court of Appeals Reversal Of The Injunction Against Enforcement Actions Pending An Administrative Hearing Conflicts With The *Bentex* Case In This Court And A Recent Decision Of The Tenth Circuit. The action taken by the district court here—to enjoin FDA from enforcement action pending completion of the administrative hearing on the status of Benylin—was the mirror image of action taken by the district court in the *Bentex* case which this Court upheld in 412 U.S. 645.

In *Bentex*, as in this case, there was a question as to whether a drug was a "new" or an "old" drug and whether it could be sold OTC or only on a prescription basis. The district court declined to issue a declaratory judgment on the status of the product, holding that that was a matter within the primary jurisdiction of FDA. Pending completion of an administrative hearing by FDA to determine the status of the drug, the district court enjoined FDA from enforcement actions against continued OTC sale of the drug. In so doing the *Bentex* district court said:

> "The situation revealed by the record to date convinces the court that the status quo must be

[18]For example, in *Nor-Am Agricultural Products, Inc.* v. *Hardin*, a panel of the Seventh Circuit split 2-1 in holding that *Abbott Laboratories*, not *Ewing*, governed a pre-enforcement review case under a Department of Agriculture regulatory program similar to FDA's. An injunction against enforcement action pending an administrative hearing was affirmed. 435 F. 2d 1133 (1970). On rehearing *en banc* however, the court held 4-2 that *Ewing* controlled and ordered the complaint dismissed. 435 F.2d 1151 (1970), *petition for cert. dismissed*, 402 U.S. 935 (1971). The First Circuit in *Natick Paperboard Corp.* v. *Weinberger*, 498 F.2d 125 (1974)—in which, unlike this case, the product was alleged to be toxic—split the difference: it held that *Ewing* prevented the grant of an injunction, but that *Abbott Laboratories* permitted the court to proceed to the merits of the legal issue presented there (*i.e.*, whether the product was within the FDA's statutory authority).

> preserved until such time as the plaintiffs have an opportunity to be heard on the merits of their contention. Therefore, the court will enjoin the defendants from instituting actions against the plaintiffs on account of such of their products as are presently marketed . . .; and the defendants are hereby enjoined from instituting any action against the plaintiffs herein for the cause stated above until such time as there has been a determination that the products in question are new drugs."[19]

The government did not appeal. In upholding the action of the *Bentex* district court this Court specifically noted that the district court had "entered an injunction to preserve the status quo" while FDA resolved the " 'new drug' issue in an administrative proceeding." 412 U.S. at 648.

The court of appeals reversal of the district court's injunction pending completion of the hearing on the status of Benylin is in conflict with *Bentex*. Indeed, the court of appeals stands *Bentex* on its head by citing it for the proposition that the seizure court could wait for "an appropriate administrative declaration before it acted" (App. A at 13a). First, there were no seizure courts in *Bentex* because the injunction had prevented seizure. Second, the statement in *Bentex* about waiting means only that that court was to wait for FDA to decide the status of the product in the exercise of its primary jurisdiction.[20] That is just what would have happened here if the court of appeals had

[19] *O'Neal, Jones & Feldman, Inc.* v. *Richardson*, Civ. A. No. 70-1001 (D.S.C., February 10, 1971), *rev'd sub nom. Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F.2d 363 (4th Cir. 1972), *aff'd sub nom. Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973), App. G at 99a-100a.

[20] Indeed since, as the court of appeals said, the seizure courts should await the administrative hearing before acting (App. A at 13a), it could hardly have been "an abuse of discretion" (*id.*) for the district court to assure that no seizure actions were initiated pending that hearing.

affirmed the district court, as it should have. Nothing in *Bentex* suggests that subsequent seizure actions can abort pre-enforcement review or afford adequate relief in circumstances such as were presented in *Bentex* and in this case.

Nor can the court of appeals decision be justified on the ground that the seizure actions necessarily provide "an adequate remedy" (App. A at 12a). The court of appeals held that the possibility of review by the seizure courts made it an abuse of discretion for the pre-enforcement court to enjoin enforcement actions, even though the pre-enforcement court concededly had jurisdiction to consider the challenge to "the regulations and procedures of the FDA" (App. A at 13a). That holding conflicts with this Court's recognition in *Abbott Laboratories* that because of the "sensitive" nature of the drug industry, companies like Parke-Davis can be "severely and unnecessarily" harmed if they can challenge FDA actions "only as a defense to an action brought by the Government . . ." (*id.* at 153).

Finally, the decision below also conflicts with the decision of the Tenth Circuit in *Rutherford* v. *United States*, 542 F.2d 1137, 1143-44 (1976), which, like *Bentex*, approved the grant of a preliminary injunction against FDA enforcement action while FDA conducted an administrative proceeding to determine whether a particular substance was a "new drug." Resolution of this conflict also justifies review by this Court.

CONCLUSION

For the foregoing reasons, a writ of certiorari should issue to review the judgment and opinion of the Court of Appeals for the Sixth Circuit.

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